Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect and side effects of Azitromycin and co-Amoxiclav in the treatment of acute bacterial sinusitis in adults.

Protocol summary

Summary

The aim of this study is the comparison effect of Azitromycin and Co_amoxiclav on acute sinusitis in adults. This study is a double blind clinical trial. the population have studied are patients with acute sinusitis and between 12-65 years old. Inclusion criteria: Existing at least two major criteria or one major criteria and two minor criteria. Major criteria are: facial pain; nasal obstruction and.... Minor criteria: headache; halitosis and... . Exclusion criteria: Patients with chronic sinusitis; patients with recurrent sinusitis; patients with anatomical disorders (severe septal deviation; cleft palate; nasal poliposis) and... .Sample size are 90. The patients are divided in two groups: First group are prescribed one tablet Azitromycin 500 mg daily for three days, second group are prescribed Co_amoxiclav capsule 625 mg every 8 hours for 10 days. This study has done in the spring and summer of the 2013. In the end of the study, the patients with no evidence of acute sinusitis criteria considered cured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505106252N7**
Registration date: **2015-06-02, 1394/03/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

Name

Soroush Amani

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1226 4834

Email address

samani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect and side effects of Azitromycin and co- Amoxiclav in the treatment of acute bacterial sinusitis in adults.

Public title

Comparison of the effect of Azitromycin and co-Amoxiclav in the treatment of adult sinusitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Existing at least two major criteria or one major criteria and two minor criteria that lasting at least 7 days and at most 28 days. Major criteria are: facial pain or pressure; facial fullness or congestion; nasal obstruction; purulent rhinorrhea or postnasal discharge; loss of smell; fever. Minor criteria: headache; halitosis; fatigue; toothache; cough; otalgia; fullness of

ear. Exclusion criteria: Patients with chronic sinusitis; patients with recurrent sinusitis; patients with anatomical disorders(severe septal deviation; cleft palate; nasal poliposis; patients with chronic disorders (severe hepatic disease; renal disease; heart disease and asthma); women in pregnancy and breast feeding; history of sensitivity to co_ amoxiclav or azitromycin; patients with cilliary dysfunction; cystic fibrosis; congenital or acquired immune deficiency (HIV; diabetes); complications of sinusitis; antibiotic consumption in last one month; patients less than 12 years old or more than 65 years old.

Age
From **12 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sharekord University of Medical Sciences

Street address
Kashani Avenue, Shahrekord

City
Shahrekod

Postal code
8815713471

Approval date
2013-10-12, 1392/07/20

Ethics committee reference number
24-6-92

Health conditions studied

1

Description of health condition studied
Acute sinusitis

ICD-10 code
J01.9

ICD-10 code description
Acute sinusitis, unspecified

Primary outcomes

1

Description
Facial pain

Timepoint
fifth day, tenth day

Method of measurement
clinical evaluation

2

Description
Feeling of fullness or congestion of the face

Timepoint
fifth day, tenth day

Method of measurement
clinical evaluation

3

Description
Nasal obstruction

Timepoint
fifth day, tenth day

Method of measurement
clinical evaluation

4

Description
Purulent discharge of nose or postnasal discharge

Timepoint
fifth day, tenth day

Method of measurement
clinical evaluation

5

Description
Loss of smell

Timepoint
fifth day, tenth day

Method of measurement
clinical evaluation

6

Description
Fever

Timepoint
fifth day, tenth day

Method of measurement
cheking with termometer

Secondary outcomes

1

Description
Headache
Timepoint
fifth day, tenth day
Method of measurement
history

2

Description
Hallitosis
Timepoint
fifth day, tenth day
Method of measurement
history

3

Description
Fatigue
Timepoint
fifth day, tenth day
Method of measurement
history

4

Description
Toothache
Timepoint
fifth day, tenth day
Method of measurement
history

5

Description
Cough
Timepoint
fifth day, tenth day
Method of measurement
history

6

Description
Otalgia or feeling of fullness in the ear
Timepoint
fifth day, tenth day
Method of measurement
history

Intervention groups

1

Description
In the first group Azitromycin 500 mg tablet was prescribed daily for three days.
Category
Treatment - Drugs

2

Description
In the second group Co-Amoxiclav 625 capsule was prescribed every eight hours for ten days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Soroush Amani MD
Street address
Shariati Avenue, Shahrekord
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Mahmood Mobasheri MD
Street address
Kashani Avenue, Shahrekord
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences

Full name of responsible person
Soroush Amani MD
Position
Otolaryngologist
Other areas of specialty/work
Street address
Kashani Avenue, Shahrekord
City
Shahrekord
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
+98 38 3334 3004
Email
info@Skums.ac.ir
Web page address
http://www.SKUMS.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sharkord University of Medical Sciences
Full name of responsible person
Soroush Amani MD
Position
Otolaryngologist
Other areas of specialty/work
Street address
Kashani Avenue, Shahrekord
City
Shahrekord
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
+98 38 3334 3004
Email
info@Skums.ac.ir
Web page address
http://www.SKUMS.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Soroush Amani MD
Position
Otolaryngologist
Other areas of specialty/work
Street address
Kashsni Avenue, Shahrekord
City
Shahrekord
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
+98 38 3334 3004
Email
info@Skums.ac.ir
Web page address
http://www.SKUMS.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty